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EXAMINER	
GEDEON, BRIAN T	
ART UNIT	PAPER NUMBER
3766	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/799,271	GARABEDIAN ET AL.	
	Examiner	Art Unit	
	Brian T. Gedeon	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,18-23,37-47 and 126-177* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *146-161* is/are allowed.

6)☒ Claim(s) *1-9, 18-23, 37-47, 126-135, 140-145, and 162-177* is/are rejected.

7)☒ Claim(s) *136-139* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/22/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 January 2008 has been entered.

Information Disclosure Statement

2. The information disclosure statement filed 22 January 2008 has been considered.

Drawings

3. The objection made to the drawings in the previous Office action has been withdrawn in view of Applicant's remarks submitted with the request for continued examination.

Claim Rejections - 35 USC § 112

4. The 35 U.S.C. 112, second paragraph, rejection against claims 1-9, 18, and 19 has been withdrawn in view of the amendments to the claim.

Claim Objections

5. Claims 8, 9, 18, and 19 are objected to because of the following informalities: claims 8, 9, 19, and 19 depend from non-existent claim 0. Appropriate correction is required.

Allowable Subject Matter

6. The indicated allowability of claims 37-47, 126-145, and 162-177 is withdrawn based on the review of the reference(s) to Vinup et al. (US Patent no. 7,072,719). Rejections based on the cited reference(s) follow.

7. Claims 146-161 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: The cited prior art does not teach or suggest disengaging the second lead body from the first lead body by bowing out the second lead body portion from the first lead body portion.

8. Claims 136-139 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The cited prior art does not teach or suggest altering the geometry of the second lead by either having a pre-curved form or by use of a pullwire.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-2, 4-10, 18, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Vinup et al. (US Patent no. 7,072,719).

In regard to claim 1, Vinup et al. disclose a neurological stimulation system 20 with stimulation leads 24 and 26 with interlocking elements 23, col 1 lines 28-39. Figures 2-5 show a plurality of medical leads which allow for implantation of paddle or surgical style leads using percutaneous methods without the use of a large needle or introducer, col 2 lines 40-49. The leads are axially engaged to one another. The lead bodies are axially engaged to one another by a wide variety of complementary coupling geometries, such as a rail and groove embodiment as depicted in figures 6a-7b, col 3 lines 46-54. Vinup et al. disclose that the method for inserting the neurological leads involves introducing a first lead through a needle or introducer, then engaging the coupling mechanism (detail 46) of the second lead body using the first lead body coupling mechanism (detail 40) as a guide, col 3 line 55 – col 4 line 2. In view of the method described by Vinup for insertion of the second lead body using the first lead body as a guide, it is considered that the second lead is being slidably inserted along

the first lead, wherein the leads can be slidably engaged along the rail and groove coupling mechanism. It can also be seen in figures 2-5 show the first and second leads being of different lengths wherein the first lead 26 is slightly longer than the second lead 24.

Further in regard to claims 1 and 37, figure 1 illustrates that lead bodies 24 and 26 extending from the lower spine namely the proximal end of leads bodies 24 and 26 extend from the lower spine where they are coupled to a neurostimulation pulse generator housing 22. The Examiner considers the leads of Vinup et al. to be capable of performing such a function, since it is known in the art that neurostimulation pulse generator housings are sometimes implanted and sometimes kept external to the patient wherein the leads would have to extend through an opening in the patient's skin in order to connect to the generator housing.

In regard to claim 2, the lead bodies are cylindrically shaped, figures 6a-6c.

In regard to claims 4, 5, and 7, the stimulation leads of Vinup et al. have at least one electrode, col 2 lines 50-58.

In regard to claim 6, figures 2-4 of Vinup et al. show the electrodes 34 facing in a single direction when the leads are engaged with one another.

In regard to claims 8 and 9, the complementary coupling mechanisms 23, are rail and groove embodiment, extending axially along the leads, col 3 lines 46-54.

In regard to claim 10, figures 2-5 show the first and second leads being of different lengths.

In regard to claim 18, figures 2-4, 6a-6c, and 9a-9c, shows various embodiments where a plurality of leads can be engaged to one another by means of complementary coupling mechanisms being axially located on both sides of a single lead.

In regard to claim 19, a neurological stimulator 22 is coupled to the stimulation leads, col 2 lines 29-32.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 3, 20-23 and 33-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vinup et al. (US Patent no. 7,072,719) as applied to claims 1 and 24, and further in view of Cross, Jr. et al. (US Patent no. 6,578,733 – hereinafter Cross).

In regard to claim 3, Vinup et al. disclose the claimed invention with the exception of specific dimensions for the cross-sectional area of the first and second elongated bodies. It would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize 5 mm or less for the said elongated bodies since our reviewing courts have held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC*

Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

In regard to claims 20, 22, 33, 35, 37, 39, and 46, Vinup et al. describe the invention as claimed including inserting a first stimulation lead at a predetermined position, then guides at least a second stimulation lead along the first stimulation lead, wherein the leads are coupled together by means of a complementary coupling mechanism, col 3 lines 46-67. The leads are configured to be coupled together and stimulate neurological tissue (i.e., nerves or muscle tissue) in a desired location, col 2 lines 33-36. Vinup et al. disclose that the method for inserting the neurological leads involves introducing a first lead through a needle or introducer, then engaging the coupling mechanism (detail 46) of the second lead body using the first lead body coupling mechanism (detail 40) as a guide, col 3 line 55 – col 4 line 2. In view of the method described by Vinup for insertion of the second lead body using the first lead body as a guide, it is considered that the second lead is being slidably inserted along the first lead, wherein the leads can be slidably engaged along the rail and groove coupling mechanism. However, Vinup et al. do not teach that the leads are inserted into the epidural space around the spinal cord. Cross, in a similar field of endeavor, discloses a percutaneous surgical lead, wherein two lead bodies 12 and 14 are axially coupled together and inserted into the spinal cord. Cross also teaches that stimulation of the spinal cord often is accomplished by implanting medical leads into the epidural space of the spinal cavity, col 1 lines 20-23. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method

of Vinup et al. with the teachings of Cross since Vinup et al. teach that the stimulation lead can percutaneously be implanted in a desired spot to stimulate nerve tissue and Cross teaches that it is known in the art to stimulate nerve tissue in the epidural space of the spinal cord by means of an electrical lead, particularly electrical leads that are axially coupled together.

In regard to claims 21, 34, and 38, Vinup et al. teach that the stimulation leads are percutaneously inserted into the desired space, col 2 lines 40-49.

In regard to claims 23, 36, and 41, Vinup et al. teach that neurological stimulation is known to treat chronic pain, col 1 lines 13-18.

In regard to claim 40, the stimulation leads of Vinup et al. are connected to a neurological stimulator 22, col 2 lines 28-39.

In regard to claim 42-44, the objective of Vinup et al. is to apply electrical stimulation to neural tissue in any desired location, col 28-39. Figure 1 shows the leads implanted near the spine.

In regard to claim 45, figures 2-4, 6a-6c, 9a-9b of Vinup et al., show a plurality of leads, including three, engaged to one another.

In regard to claim 47, Vinup et al. teach that a needle or introducer, col 3 lines 57-60, introduce the stimulation leads into percutaneous space.

13. Claims 126-145 and 162-177 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Vinup ET al. (US Patent no. 7,072,719).

In regard to claims 126, 133, 142, 162, 169, and 174, Vinup et al. substantially describe the invention as claimed. However, it is not taught by Vinup et al. that second

lead body is configured to deploy from the first lead body by slidably disengaging at least a portion of the complementary coupling mechanisms; nor does Vinup et al. teach away from configuring the second lead body from slidably disengaging the first lead body. The Examiner considers that the groove and rail, col 3 lines 46-54, coupling mechanism described by Vinup et al. is capable of performing such a function since it is implied by Vinup et al. that the coupling mechanism runs the entire axially length of the lead all the way to the distal tip with there being a termination point such that a second lead can be inserted along the first lead and extend beyond the distal end of the first lead as illustrated in figures 2-4. Once the distal end of the second lead extends beyond the distal end of the first lead, it is considered to be a portion of the lead that has been disengaged from the coupling mechanisms.

In regard to claims 127 and 163, the lead bodies are cylindrically shaped, figures 6a-6c.

In regard to claims 128 and 164, Vinup et al. disclose the claimed invention with the exception of specific dimensions for the cross-sectional area of the first and second elongated bodies. It would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize 5 mm or less for the said elongated bodies since our reviewing courts have held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner*

v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

In regard to claims 129, 130, 132, 165, 166, and 168, the stimulation leads of Vinup et al. have at least one electrode, col 2 lines 50-58.

In regard to claims 131 and 167, figures 2-4 of Vinup et al. show the electrodes 34 facing in a single direction when the leads are engaged with one another.

In regard to claims 134 and 170, the complementary coupling mechanisms 23, are rail and groove embodiment, extending axially along the leads, col 3 lines 46-54.

In regard to claims 135 and 171, figures 2-5 show the first and second leads being of different lengths.

In regard to claims 140 and 172, figures 2-4, 6a-6c, 9a-9b of Vinup et al., show a plurality of leads, including three, engaged to one another.

In regard to claims 141 and 173, a neurological stimulator 22 is coupled to the stimulation leads, col 2 lines 29-32.

In regard to claims 143 and 175, Vinup et al. teach that the stimulation leads are percutaneously inserted into the desired space, col 2 lines 40-49.

In regard to claims 144 and 176, the objective of Vinup et al. is to apply electrical stimulation to neural tissue in any desired location, col 28-39. Figure 1 shows the leads implanted near the spine.

In regard to claims 145 and 177, Vinup et al. teach that neurological stimulation is known to treat chronic pain, col 1 lines 13-18.

Response to Arguments

14. The rejections made against the pending claims have be reiterated and rearticulated above to better address subject matter as claimed and amended.

15. Applicant's arguments filed 22 January 2008 have been fully considered but they are not persuasive.

In regard to Applicant's arguments pertaining to claims 1, 2, 4-9, 18 and 19, that because Vinup et al. illustrate the distal end of the first lead body 23 axially extending beyond the distal end of the second lead body 26, does not mean that the first lead body 23 is longer than the second lead body 26, the Examiner respectfully disagrees. First, the illustration provides ample suggestion that it is certainly possible for one lead to be longer than the second lead; the illustration itself shows this. Second, neither Vinup et al. nor the Applicant have shown any evidence why this possibility cannot be true.

Further in regard to Applicant's arguments pertaining to claims 1, 2, 4-9, 18 and 19, that Vinup et al. do not provide either express or inherent disclosure that the proximal end of the lead bodies extends from an opening in the patient's back, the Examiner respectfully disagrees. Figure 1 of Vinup et al. show the proximal end of lead bodies 24 and 26 extending from the lower end of the patient's back. Further, the Examiner considers Applicant's limitations regarding this matter to be a functional use recitation in that there is no structural limitation recited that differentiates the proximal ends of the claimed lead from the proximal ends of the lead described by Vinup et al. Nor is there any evidence demonstrating that the leads described by Vinup et al. are

incapable of performing the function as claimed. It has been held that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In regard to Applicant's arguments pertaining to claims 3 and 20-23, that the combination of Vinup et al. and Cross is improper because Vinup et al. fails to teach or suggest the limitations of the claims from which 3 and 20-23 depend from is considered moot in view of the discussion pertaining to Vinup et al. in relation to the base claims above.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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